TruQuick™ H. pylori Ag 25T

A rapid test for the qualitative detection of *Helicobacter pylori* (*H. pylori*) antigens in feces.

REF **TQ5725** IVD **Rx Only**

INTENDED USE
TruQuick H. pylori Ag is a rapid immunoassay for the qualitative detection of *H. pylori* antigens in feces specimens to aid in the diagnosis of *H. pylori* infection.

SUMMARY AND EXPLANATION OF THE TEST
H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.[1, 2] Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.[3] A very common approach to the diagnosis of *H. pylori* infection is the serological identification of specific antibodies in infected patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organisms.[4] HpSA (*H. pylori* Stool Antigen) testing is gaining popularity for diagnosis of *H. pylori* infection and also for monitoring the efficacy of the treatment of *H. pylori* infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H. pylori*.[5]

TruQuick H. pylori Ag is a rapid immunoassay for the qualitative detection of *H. pylori* antigens in feces specimens, providing results in ten minutes. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H. pylori* antigens in human feces specimens.

BIOLOGICAL PRINCIPLES
TruQuick H. pylori Ag is a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in feces specimens. In this test, the membrane is precoated with anti-*H. pylori* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*H. pylori* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*H. pylori* antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: Each cassette is packaged in a foil pouch.
- Specimen Collection Tubes with Extraction Buffer: Extraction Buffer contains Proclin 300 as a preservative.
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Pipette and disposable tips (optional)
- Timer
- Droppers

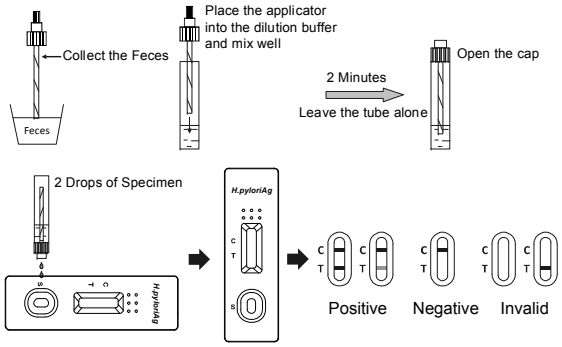
PRECAUTIONS
1. All reagents are for in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
The kit can be stored at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The Test Cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
2. Bring the necessary reagents to room temperature before use.
3. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 C if not tested within 6 hours. For long term storage, specimens should be kept below -20 C.
2. To process fecal specimens:
   - For Solid Specimens:
     Unscrew the cap of the Specimen Collection Tube then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - For Liquid Specimens:
     Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the Specimen Collection Tube containing the Extraction Buffer.
     Tighten the cap onto the Specimen Collection Tube, then shake the Specimen Collection Tube vigorously to mix the specimen and the Extraction Buffer. Leave the tube alone for 2 minutes.
3. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the Specimen Collection Tube upright and open the cap onto the Specimen Collection Tube. Invert the Specimen Collection Tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the Test Cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Read results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.
   Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new Test Cassette and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department at 800-343-3858 or your local distributor

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick H. pylori Ag has been compared with Endoscope-based methods, demonstrating an overall correlation of 98.6%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick H. pylori Ag is for in vitro diagnostic use only. The test should be used for the detection of *H. pylori* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antigens concentration can be determined by this qualitative test.
2. TruQuick H. pylori Ag will only indicate the presence of *H. pylori* in the specimen and should not be used as the sole criteria for *H. pylori* to be etiological agent for peptic or duodenal ulcer.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.
5. Following certain antibiotic treatments, the concentration of *H. pylori* antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick H. pylori Ag was evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of TruQuick H. pylori Ag is 98.8% and the specificity is 98.4% relative to Endoscope-based methods.

Method		Endoscope-based method		Total Result
TruQuick H. pylori Ag	Results	Positive	Negative	
	Positive	168	3	171
	Negative	2	189	191
Total Result		170	192	362

Sensitivity: 98.8% (95% CI*: 95.8%-99.9%)
Specificity: 98.4% (95% CI*: 95.5%-99.7%)
Correlation: 98.6% (95% CI*: 96.8%-99.5%) *Confidence Interval

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 15 replicates of three specimens: negative, low positive, and high positive specimens. The specimens were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 15 independent assays on the same three specimens: negative, low positive, and high positive specimens. Three different lots of the TruQuick H. pylori Ag were tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
Crossreactivity with following organisms has been studied at 1 x 10^9 organisms/mL. The following organisms were found negative when tested with TruQuick H. pylori Ag:

Acinetobacter calcoaceticus	Acinetobacter spp	Branhamella catarrhalis
Candida albicans	Chlamydia trachomatis	Enterococcus faecium
E.coli	Enterococcus faecalis	Gardnerella vaginalis
Group A Streptococcus	Group B Streptococcus	Group C Streptococcus
Hemophilus influenza	Klebsiella pneumonia	Neisseria gonorrhea
Neisseria meningitides	Proteus mirabilis	Proteus vulgaris
Pseudomonas aeruginosa	Rotavirus	Salmonella choleraesius
Staphylococcus aureus	Adenovirus	

ANALYTICAL SENSITIVITY
The analytical sensitivity for this device is 1 x 10^7 organisms/mL of Buffer. There is no high dose effect observed with this product at antigen concentrations up to 2.5 x 10^{10}.

TESTS FOR INTERFERING SUBSTANCES
The following analytes were found nonreactive when spiked into diluting Buffer and a moderate positive sample.

Ascorbic acid 20 mg/dL	Urea 2 g/dL
Oxalic Acid 60 mg/dL	Glucose 2 g/dL
Bilirubin 100 mg/dL	Caffeine 40 mg/dL
Uric acid 60 mg/dL	Albumin 2000 mg/dL
Acetylsalicylic acid 20 mg/dL	

REFERENCES

1. Marshall BJ, McGechie DB, Rogers PAR, Glancy RG. Pyloric Campylobacter infection and gastroduodenal disease. Med J Australia 1985;149:439-44.
2. Soll AH. Pathogenesis of peptic ulcer and implications for therapy. N Engl J Med 1990;322:909-16.
3. Hazell SL, et al. Campylobacter pyloridis and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Am J Gastroenterol 1987;82(4):292-96.
4. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am J Med 1996;100:35S-41S.
5. Anand BS, Raed AK, Malaty HM, et al. Low point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol 1996;91:1112-1115.

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	R_x Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.